

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

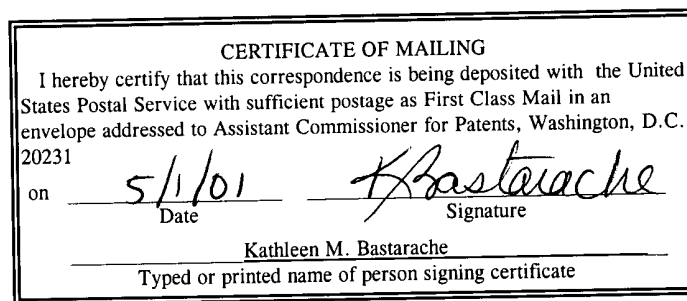
- Applicants

Laurie J. Ozelius and Xandra O. Breakefield

Application No.: 09/772,105 Group Art Unit: 1645

Filed: January 26, 2001 Examiner: Not provided

Title: Torsin, Torsin Related Genes and Methods of Detecting Neuronal Diseases



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references were provided with prior application, U.S. Application No. 09/461,921, to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: May 1, 2001

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
0838.1001-009

APPLICATION NO.  
09/772,105

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

APPLICANT

Laurie J. Ozelius and Xandra O. Breakefield

FILING DATE

January 26, 2001

GROUP

1645

March 28, 2001

## U.S. PATENT DOCUMENTS

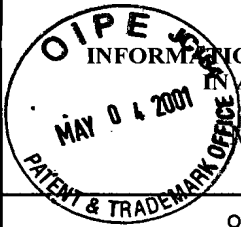
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,407,821	04/18/95	Breakefield et al.	435	6	
	AB						

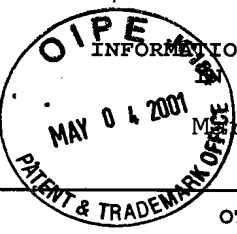
## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 97/07669	6 Mar 97	PCT			
	AM	0 398 709	17 May 90	EP			
	AN						

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	AR	Augood, S. et al., "Expression of the Early-Onset Torsion Dystonia Gene (DYT1) in Human Brain," <i>Ann. Neurol.</i> 43:669-673 (May 1998).					
2	AS	Augood, S. et al., "Distribution of the mRNAs Encoding TorsinA and TorsinB in the Normal Adult Human Brain," <i>Ann. Neurol.</i> , 46:761-769 (1999)					
3	AT	Breakefield, X. et al., "Linkage Analysis in a Family with Dominantly Inherited Torsion Dystonia: Exclusion of the Pro-Opiomelanocortin and Glutamic Acid Decarboxylase Genes and Other Chromosomal Regions Using DNA Polymorphisms," <i>J. Neurogenet.</i> 3:159-175 (1986).					
4	AU	Breakefield, X. et al., "Early Onset Torsion Dystonia Caused by Dominant Defect in ATP-Binding Protein," <i>Society for Neuroscience Abstracts</i> 23:1962, Abstract 764.1 (1997).					
5	AV	Bressman, S. et al., "Idiopathic Dystonia Among Ashkenazi Jew: Evidence for Autosomal Dominant Inheritance," <i>Ann. Neurol.</i> 26:612-620 (1989).					
6	AW	Bressman, S. et al., "A Study of idiopathic torsion dystonia in a non-Jewish family: Evidence for genetic heterogeneity," <i>Neurology</i> 44:283-287(1994).					
7	AX	Bressman, S. et al., "Dystonia in Ashkenazi Jews: Clinical Characterization of a Founder Mutation," <i>Ann. Neurol.</i> 36:771-777 (1994).					
8	AY	Bressman, S. et al., "Secondary dystonia and the DYT1 gene" <i>Neurology</i> 48:1571-1577 (1997).					
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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 0838.1001-009	APPLICATION NO. 09/772,105
		APPLICANT Laurie J. Ozelius and Xandra O. Breakefield	
		FILING DATE January 26, 2001	GROUP 1645
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
10	AR2	Dobyns, W. et al., "Rapid-onset dystonia-parkinsonism," <i>Neurology</i> 43:2596-2602 (1993).	
11	AS2	Dunbar, C., "Gene Transfer to Hematopoietic Stem Cells: Implications for Gene Therapy of Human Disease," <i>Annu. Rev. Med.</i> 47:11-20 (1996).	
12	AT2	Gasser, T. et al., "Haplotype Analysis at the DYT1 Locus in Ashkenazi Jewish Patients with Occupational Hand Dystonia," <i>Movement Disorders</i> 11:163-166 (1996).	
13	AU2	Geller, A. and Breakefield, X., "A Defective HSV-1 Vector Expresses <i>Escherichia coli</i> $\beta$ -Galactosidase in Cultured Peripheral Neurons," <i>Science</i> , 241:1667-1669 (1988).	
14	AV2	Gasser, T. et al., "The Autosomal Dominant Dystonias," <i>Brain Pathology</i> 2:297-308 (1992).	
15	AW2	Holmgren, G. et al., "Adult onset idiopathic torsion dystonia is excluded from the DYT 1 region (9q34) in a Swedish family," <i>J. Neurol. Neurosurg. Psychiatry</i> 59:178-181 (1995).	
16	AX2	Inzelberg, R. et al., "A Genetic Study of Idiopathic Torsion Dystonia in Israel," <i>Neurology</i> 46(2) Suppl. A172: (1996).	
17	AY2	Klein, C. et al., "Clinical and Genetic Evaluation of a Family with a Mixed Dystonia Phenotype from South Tyrol," <i>Annals of Neurology</i> 44(3): 394-398 (1998).	
18	AZ2	Klein, C. et al., "De novo mutations (GAG deletion) in the DYT1 gene in two non-Jewish patients with early-onset dystonia," <i>Human Molecular Genetics</i> 7:1133-1136 (1998).	
19	AR3	Klein, C. et al., "A Genetic Study of 72 Patients with Idiopathic Focal Dystonia from Northern Germany," <i>Neurology</i> 50(4) Suppl. 4:A116-117 (1998).	
20	AS3	Klein, C. et al., "Search for a Founder Mutation in Idiopathic Focal Dystonia from Northern Germany," <i>Am. J. Hum. Genet.</i> 63:1777-1782 (1998).	
21	AT3	Klein, C. et al., "Genetic Analysis of Three Patients with an 18p-Syndrome and dystonia" <i>Neurology</i> , 649-651 (1999)	
22	AU3	Kramer, P. et al., "Dystonia Gene in Ashkenazi Jewish Population Is Located on Chromosome 9q32-34," <i>Ann. Neurol.</i> 27:114-120 (1990).	
23	AV3	Kramer, P. et al., "The DYT1 Gene on 9q34 Is Responsible for Most Cases of Early Limb-Onset Idiopathic Torsin Dystonia in Non-Jews," <i>Am. J. Hum. Genet.</i> 55:468-475 (1994).	
24	AW3	Kwiatkoski, D. et al., "Torsion Dystonia Genes in Two Populations Confined to a Small Region on Chromosome 9q32-34," <i>Am. J. Hum. Genet.</i> 49:366-371 (1991).	
25	AX3	Ozelius, L., Ph.D. Dissertation (Breakefield, X.O. - Advisor) "Definition of the Region of Human Chromosome 9Q Containing a Dystonia Gene," Vol. 55-08B, pp 3124, 156 pages, Harvard University (1994).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
26	AY3	Ozelius, L. et al., "Human Gene for Torsion Dystonia Located on Chromosome 9q32-q34," <i>Neuron</i> 2:1427-1434 (1989).	
27	AZ3	Ozelius, L. et al., "Strong Allelic Association between the Torsion Dystonia Gene (DYT1) and Loci on Chromosome 9q34 in Ashkenazi Jews," <i>Am. J. Hum. Gent.</i> 50:619-628 (1992).	
28	AR4	Ozelius, L. et al., "Fine Mapping of the Human Dystonia Gene (DTY1) on 9q34 and Evaluation of a Candidate cDNA" <i>American Journal of Human Genetics</i> , 51:Suppl., (1992).	
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30	AT4	Ozelius, L. et al., "The early-onset torsion dystonia gene (DYT1) encodes an ATP-binding protein," <i>Nature Genet.</i> 17:40-48 (1997).	
31	AU4	Page, C. et al., "Genetic Analysis of Three Patients with Dystonia and Deletion In Chromosome 18p," <i>Neurology</i> 50(4) Suppl. 4:A427 (1998).	
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34	AX4	Risch, N. et al., "Genetic analysis of idiopathic torsion dystonia in Ashkenazi Jews and their recent descent from a small founder population," <i>Nature Genet.</i> 9:152-159 (1995).	
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36	AZ4	Schmidt-Wolf, G. et al., "Bone Marrow and Clinical Gene Therapy," <i>J. Hematotherapy</i> 4:551-561 (1995).	
37	AR5	Shaughnessy, E. et al., "Parvoviral Vectors for the Gene Therapy of Cancer," <i>Semin. Oncology</i> 23:159-171 (1996).	
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EXAMINER		DATE CONSIDERED	